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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Indu Parikh, *et al.*	)	Examiner: Not Yet Assigned
Serial No.: Not Yet Assigned	)	Art Unit: Not Yet Assigned
Filed: December 20, 2001	)	**CLEAN COPY OF THE PENDING CLAIMS**
For: **TREATMENT FOR DIABETES**	)	

BOX Patent Application
Assistant Commissioner for Patents
PO Box 2327
Arlington, VA 22202

Sir:

The following is the text of the claims shown in the attached "Version with Markings to Show Changes Made".

IN THE CLAIMS

1. (Amended) A method for treating diabetes mellitus in an individual in need thereof, said method comprising:

administering to said individual a composition providing a gastrin/CCK receptor ligand and an EGF receptor ligand in an amount sufficient to effect differentiation of pancreatic islet precursor cells to mature insulin-secreting cells.

2. (Reiterated) The method according to Claim 1, wherein said at least one receptor ligand is an EGF receptor ligand is selected from the group consisting of EGF1-53, EGF1-48,

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(Signature)

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(Printed Name)

3. (Reiterated) The method according to Claim 2, wherein said EGF1-53, EGF1-48, or its EGF1-47 or EGF1-49 congener is human EGF1-53, EGF1-48, or its EGF1-47 or EGF1-49 or its congener.

4. (Amended) A method for providing a patient with diabetes in need thereof with a population of mature insulin-secreting β-cells, said method comprising:

providing pancreatic β-cells, outside said patient, with a sufficient amount of a gastrin/CCK receptor ligand and an epidermal growth factor receptor ligand to induce proliferation of mature insulin-secreting β-cells of said pancreatic β-cells prior to said transplanting, whereby an expanded population of mature insulin-secreting β-cells is obtained; and

transplanting into said patient said mature insulin-secreting β-cells.

5. (Reiterated) The method according to Claim 4, wherein said diabetes is Type 2 diabetes.

6. (Reiterated) The method according to Claim 4, wherein said gastrin/CCK receptor ligand is a gastrin.

7. (Reiterated) The method according to Claim 4, wherein said epidermal growth receptor ligand is TGF-α or an EGF selected from the group consisting of EGF1-53, EGF1-48, or its EGF1-47 or EGF1-49 congener.

19. (New) The method according to Claim 1, wherein said gastrin/CCK receptor ligand is a gastrin.

20. (New) Pancreatic islet precursor cells treated *ex vivo* with a sufficient amount of a gastrin/CCK receptor ligand and an EGF receptor ligand to induce proliferation of said pancreatic islet precursor cells into mature insulin-secreting β-cells, whereby an expanded

population of said mature insulin-secreting β-cells is obtained.

21. (New) A method for obtaining an expanded population of insulin-secreting pancreatic β-cells, said method comprising:

providing pancreatic islet precursor cells with a sufficient amount of a gastrin/CCK receptor ligand and an EGF receptor ligand to induce proliferation of said insulin secreting pancreatic β-cells, whereby said insulin-secreting population of pancreatic β-cells is obtained.

22. (New) The method according to Claim 21, wherein said providing is *ex vivo.*

23. (Amended) A method for treating diabetes mellitus in an individual in need thereof, said method comprising:

administering to said individual:

a composition providing a gastrin/CCK receptor ligand selected from the group consisting of gastrin and cholecystokinin; and

an EGF receptor ligand selected from the group consisting of EGF1-53, EGF1-48, or its EGF1-47 congener of EGF1-48, and an EGF1-49 congener of EGF1-48;

in an amount sufficient to effect differentiation of pancreatic islet precursor cells to mature insulin-secreting cells.

24. A method for obtaining an expanded population of insulin-secreting pancreatic β-cells *ex vivo*, said method comprising:

providing pancreatic islet precursor cells with a sufficient amount of;

a composition providing a gastrin/CCK receptor ligand selected from the group consisting of gastrin and cholecystokinin; and

an EGF receptor ligand selected from the group consisting of TGF-α, EGF1-53, EGF1-48, or its EGF1-47 congener of EGF1-48, and an EGF1-49 congener of EGF1-48;

whereby said insulin-secreting population of pancreatic β-cells is obtained.

whereby said insulin-secreting population of pancreatic β-cells is obtained.

25. A kit for use in the treatment of diabetes, comprising:

pancreatic islet precursor cells according to Claim 20.

CONCLUSION

Should the Examiner have any questions regard the above, in order to expedite prosecution, the Examiner is invited to call the undersigned.

Respectfully submitted,

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